

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner Lyle A. Alexander
ART UNIT 1743

RECEIVED

MAR 30 2001

TC 1700

In re application of
E. Alan Bates et al.
Application No. 08/935,629
Filed 09/23/97
For ASSAYING DEVICE

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper or fee referred to as being attached or enclosed) is being deposited with the U.S. Postal Service in an envelope with sufficient postage as first class mail addressed to: Commissioner for Patents, Washington, DC 20231, on

3/26/01

Signed: Daniel A. Sullivan Jr.
Typed Name: Daniel A. Sullivan, Jr.

Date of Signature: 3/23/01

TRANSMITTAL OF APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

Following on the NOTICE OF APPEAL filed 1/26/01, enclosed herewith is APPELLANT'S BRIEF in triplicate.

A check for the \$5 difference between the small entity fee of \$150 paid for the previous brief and the current fee under 37 CFR 1.17(c) is attached.

Respectfully submitted,

Daniel A. Sullivan Jr.

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Adjustment date: 03/29/2001 RHARIS1
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03/29/2001 RHARIS1 00000108 08935629
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APPELLANT'S BRIEF

Commissioner for Patents
Washington, DC 20231

(1) REAL PARTY IN INTEREST

The real party in interest is DTx, Inc., a Delaware corporation.

(2) RELATED APPEALS AND INTERFERENCES

There are no pending appeals or interferences known to appellant or the appellant's legal representative, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS

Claims 1, 8, 23-34 and 37-44 are pending, rejected and appealed. Claims 35 and 36 objected to as depending on rejected base claims but would be allowable if rewritten in independent form. Claims 2-7 and 9-22 have been canceled without prejudice or disclaimer of the subject matter thereof.

(4) STATUS OF AMENDMENTS

One amendment, entitled AMENDMENT AND STATEMENT OF INTERVIEW, was filed subsequent to the final rejection mailed 10/25/00. It was filed on 12/18/00, under the expedited procedure, and was refused entry.

(5) SUMMARY OF INVENTION

All Fig. and page references in this section are to the Figs. and specification pages of this application. A copy of the specification with line numbers is attached as Appendix II for the convenience of the Board. Locations of text inserted by amendment are indicated by the circled numbers 1-5 on page 3 and the corresponding insertions are presented on the page at the end of Appendix II. Two amendments of numerals are indicated in lines 10 and 11 of page 4. A copy of the drawings as amended is attached as Appendix III.

With reference first to Fig. 1, and as explained at page 3, lines 16-19, an assaying or drug screening device of the invention includes a cartridge/cassette 1 having a broad, lateral face 1a, a

narrow, lateral face 1b, and a narrow end face 1c. Window 2 permits viewing test results on a test strip 3. Well/opening 4, situated on the broad lateral face 1a, has a top in the area of its top edge 4a. As drawn in Fig. 1, one can see that the well/opening 4 extends from its top at edge 4a into the cartridge/cassette to surround an empty space 4b for reception of sample.

Fig. 1 in exploded view and Fig. 2 in assembled view illustrate the relationship of cap/cover 5 with cartridge/cassette 1. This relationship is explained at page 3, lines 18-25. After sample has been dropped into well/opening 4 using a pipette for instance, cap/cover 5 is put in place, as shown in Fig. 2, to seal the top of the well/opening. Space 4b becomes a chamber for retention of sample. The cap/cover 5 passes around or encircles the cartridge/cassette at 5a (Fig. 2), to constrain the cap/cover in a fluid tight relationship against the top of the well/opening.

Fig. 3, as explained at page 4, lines 1-4, shows an embodiment in which the cartridge/cassette 1 has two windows 2, two test strips 3, and two well/openings connected by a channel.

In Fig. 4 (page 4, lines 5-8), raised edge 6 and indentations 7 cooperate to insure attachment of the cartridge/cassette 1. Similar action is provided by indentation 8 and button 9 of Fig. 5 (page 4, lines 9-14).

After the cap/cover 5 has been attached, the cartridge/cassette may be placed on a photocopier for photocopying of the test results showing in window 2.

(6) ISSUES

The issues presented for review are:

Issue 1. Are claims 25-26 and 44 rejectable under 35 USC 112, second paragraph, as being indefinite?

Issue 2. Are claims 1, 8, 23-34 and 42-44 rejectable under 35 USC 102(b) on Senior (USP 5,504,013)?

Issue 3. Are claims 37-41 rejectable under 35 USC 103(a) on Senior.

Issue 4. Are claims 37-39 rejectable under 35 USC 103(a) on Senior in view of Owens et al. (USP 5,897,840) or Ullman (USP 4,624,929)?

(7) GROUPING OF CLAIMS

For the ground of rejection corresponding to Issue 1, claim 44 does not stand or fall together with claims 25 and 26.

For the ground of rejection corresponding to Issue 2, claims 1, 8, 23-34 and 42-44 do not stand or fall together.

For the ground of rejection corresponding to Issue 3, claims 37-41 do not stand or fall together.

For the ground of rejection corresponding to Issue 4, claims 37-39 do not stand or fall together.

(8) ARGUMENT

Issue 1 - Claims 25 and 26

The rejection as detailed in the paper 14 referenced in the final action mailed 10/25/00 states that claim 25 is confusing as to what is intended by the "space being empty".

The referenced space is defined in parent claim 24. In terms of the drawings, well/opening 4 in Fig. 1 is drawn so that one can look down into it, and, on this basis, applicant has specified in claim 25 that the space of claim 24 is an empty space.

Rule 75(d)(1) has been followed, in that the specification at page 3, line 19, amendment circle-3, refers to "empty space 4b" of Fig. 1.

The specification that the space is empty has special relevance in terms of a distinction over Senior, because, in Senior, bibulous member 16 fills the sample-receiving opening in Senior's housing and even protrudes out of it.

For these reasons, the specification of claim 25 that the space is empty is not confusing, but, instead, is designed to particularly point out and distinctly claim a feature which applicant regards as a distinction over Senior.

Claim 26 depends from claim 25 and consequently incorporates the wording of claim 25.

Issue 1 - Claim 44

The final rejection of 10/25/00 states that claim 44 does not fulfill the preamble that requires a means and a method steps for drug analysis. The preamble reads, "A method of using a device as claimed in claim 43 to test for drug use".

As far as the means is concerned, claim 44 references a device as claimed in claim 43. Claim 43 specifies a particular type of test strip, states that it is for testing a urine sample for drug use, and provides a well which serves for deposit of the sample.

In this context, claim 44 specifies that the method comprises the steps of dropping a urine sample into the well and then covering and sealing the well. "Comprises" leaves the claim open to other steps, and that the preamble indicates testing for drug use implies that there would be an additional step, such as "determining drug test results in the window".

The second paragraph of Section 112, however, asks that one particularly point out and distinctly claim that which applicant regards as the invention. In line with this, an intent of applicant in choosing the method steps of this claim is to focus on one of the distinctions over Senior, that the sample here is applied drop-wise into a well, whereas Senior directs a urine stream at a protruding member 16.

While claim 44 is broadly written in not expressly specifying an evaluating step, it, nevertheless, fulfills the purpose of the

second paragraph of Section 112 of allowing a drug tester to determine infringement. In the drug testing, is a device as claimed in claim 43 being used, is a urine sample being added drop-wise into the well, and is the well then covered and sealed?

Breadth of a claim is not indefiniteness. Manual of Patent Examining Procedure (MPEP) 2173.04.

Issue 2 - Introduction

A basic principle of rejections under 35 USC 102(b) is that the reference must show every feature mentioned in the claims. MPEP 2131, entitled "Anticipation - Application of 35 USC 102(a), (b), and (e)", quotes as follows: Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) - "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."; Richardson v. Suzuki Motor Co., 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) - "The identical invention must be shown in as complete detail as is contained in the ... claim."

Before showing how the individual claims avoid anticipation rejections on Senior, it will be helpful to point out, in general, that the present invention and Senior differ fundamentally in approach. Thus, as brought out, for instance, on page 3 of the present specification, lines 18 and 19, sample measured in drops is of concern, and the structural characteristics and methodology set forth in the claims are chosen correspondingly. The intentions of

Senior are entirely different. In Senior, urine is not added dropwise, but, instead, an inundation of a bibulous member 16 occurs using a stream of urine. See, for instance, Senior col. 2, lines 20 and 26, and col. 4, line 45. With member 16 then soaked, it is proposed in Senior to remove cap 15 from a window 17, bring the cap around, and slide the cap over member 16 into place on portion 13. Needless to say, and despite the wishes of Senior, this provides numerous opportunities for urine to drip or be squeezed from member 16 onto hands, clothes, furniture and floor. Furthermore, there is opportunity to come into contact with the soaked member 16. Another difficulty is that member 16 can be hit and bent during the process of attempting to slide the cap over it.

There follows, now, a detailing of the manner in which the separate claims under Issue 2 avoid anticipation by Senior. For dependent claims, often only their relevant additional features are specified, it being understood that previously specified features of the parent claim or claims apply as well. In the case of some dependent claims, however, cooperation of their features with those of parent claims are especially pointed out.

Issue 2 - Claim 1

Claim 1 specifies that the cap/cover seals the top of the well/opening in a fluid tight relationship. In Senior, the opening is in the end of portion 13. Member 16 protrudes out of the opening. When cap 15 is in place, sample can still move out of the

top of the opening, into the protruding member 16. In Senior, to the extent that there may be a sealing action performed by Senior's cap 15, it appears to be along the sides of extended portion 13, rather than at the top of the opening. However, there is no exact specification in Senior of where a sealing action is located between the cap 15 and the extended portion 13 or casing 10.

Paragraph a. in col. 5 of Senior has been noted, but this does not inherently lead to a structure where the cap seals the top of the aperture. For instance, said paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. This would not change the fact that sample could still move out of Senior's opening, into the interior of cap 15 and that any sealing appears to be along the sides of extended portion 13.

The situation in Senior is to be contrasted with the situation in the present invention which has the top of the well/opening sealed in a fluid tight relationship.

Issue 2 - Claim 8

Independent claim 8 adds over claim 1 the specification of a drug screening device in the preamble and a drug test strip in the body of the claim. Senior does not disclose either a drug screening device or a drug test strip, and instead mentions pregnancy testing (Senior col. 1, line 8, and col. 2, line 54), so that claim 8 avoids the anticipation rejection for these reasons in addition to the reasons discussed above for claim 1.

Issue 2 - Claim 23

This claim is for a method of using the assaying device of claim 1 and includes steps of depositing the sample into the well/opening (the example disclosed is dropping sample from a pipette) and attaching the cap/cover means to seal the top of the well/opening in a fluid tight relationship. Senior, in contrast, runs a stream of urine against a bibulous member 16 and does not seal the top of the opening in the end of extended portion 13.

Issue 2 - Claim 24

This claim provides that there is a sample-receiving space extending into the cartridge/cassette means from the sealable top of the well/opening. While Senior's col. 1, line 52, col. 4, line 16, and col. 5, line 30, may indicate that the bibulous member has some extent from the opening of extension 13 into its interior, Senior does not disclose the association of a sealable top and a sample-receiving space extending inwards therefrom, as required by this claim 24.

Issue 2 - Claim 25

Claim 25 specifies that the space defined in claim 24 is empty. In contrast, bibulous member 16 fills the opening in the end of extended portion 13 in Senior. Paragraph a. in col. 5 of Senior does not inherently disclose a structure meeting the feature of claim 25, because paragraph a. could be accomplished by cutting member 16 off flush with the end of portion 13. Directing a urine

stream (Senior, e.g., col. 4, line 45) into an empty space of this claim 25 would result in turbulence, overflow, and splashing. The apparatus of Senior and that of the present invention have differing structural features, to support the different ways in which they are to be used.

The opinion is expressed in the first paragraph on page 4 of the final action of 10/25/00 that the term "empty space" does not provide a further structural limitation and that closed claim language might be used to exclude additional elements. "Empty space" is in the nature of a negative limitation. "The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation." MPEP 2173.05(i). Applicant's purpose here is to specify a structural difference between the present invention and Senior. The present drawings show an empty space at 4b in Fig. 1. In contrast, Senior's drawings show a bibulous member 16 filling the orifice in the end of extension 13. Once the claim specifies an empty space, presence of "comprising" in a parent claim cannot be grounds for an anticipation rejection on a reference in which the allegedly similar space is filled.

The second paragraph on page 4 of the final action of 10/25/00 is understood to be reference to applicant's argument that Senior directs a stream of urine onto bibulous member 16, whereas applicant drops urine from a pipette into a well/opening

surrounding an empty space for reception of the drops. This does result in a structural difference: Senior has a bibulous member 16 filling its orifice and protruding therefrom, while the present invention has an empty space. Senior's stream into the empty space of the present invention would lead to turbulence, overflow, and splashing.

Issue 2 - Claim 26

In contrast to the sealed chamber of this claim extending from the top of the well/opening into the cartridge/cassette, Senior can have urine in its cap outside of the top of its opening.

Issue 2 - Claim 27

This claim relates to placing the well/opening such that it can face upwards in a most stable orientation of the cartridge/cassette. The cartridge/cassette is then especially resistant against tipping when and after the pipette is brought into position for deposit of sample. Senior does not disclose its opening on a broad lateral face of its extension 13, but rather on the end of the extension. Urine can drip or spill from the bibulous member onto objects below, such as a table or floor, and onto the interior surface of the cap, once the cap is in place. The location on extension 13 of the one or more apertures mentioned in paragraph a. of col. 5 of Senior is not disclosed by Senior, other than the aperture shown in Senior's drawings in the end of 13.

Issue 2 - Claims 28 and 29

These claims are directed to the features that the cap/cover means passes around or completely encircles the cartridge/cassette, in order to hold a fluid tight seal. The exact location of the possible seal discussed in Senior beginning at col. 2, line 33 is not disclosed. Neither does Senior show the combined interaction between the top of the sample well/opening and the cap/cover means resulting from the dependence of claims 28 and 29 on claim 27. Senior's cap 15 covers a broad lateral face of its extension 13, but, unlike the situation claimed here, Senior's orifice is not on that broad lateral face.

Issue 2 - Claims 30-32

Claims 30-32 correspond to claims 24-26 and combine the specially oriented well/opening of claim 27 with the features of a sample-receiving space inwards of the sealable top, the empty space, and the sample-retaining chamber. While Senior's opening is not so specially oriented, neither does it disclose the cooperation between the sealable top and the inwards lying sample space, nor does it disclose an empty space or a sample-retaining chamber inwards of the sealed top.

Issue 2 - Claims 33 and 34

These claims correspond to claims 28 and 29 but depend from claim 32, in order to group together the features of the specially oriented well/opening of claim 27, the empty space, and the sample-

retaining chamber with the features that the cap/cover means passes around or completely encircles the cartridge/cassette, in order to hold a fluid tight seal. The exact location of the possible seal discussed in Senior beginning at col. 2, line 33 is not disclosed, but, with Senior's opening being on the end of 13, Senior certainly does not disclose the sealing of the top of a well/opening on the broad lateral face of its extension 13.

Issue 2 - Claims 37 to 41

Claim 42 was added toward the goal of providing a claim which further emphasizes features of distinction of the present invention over Senior. Claim 42 first sets forth that the assaying device combines a broad, lateral face with two narrow faces. Then, it places the sample deposit well in the broad, lateral face. Only "well" is used in claim 42, rather than "well/opening", since "well" better conveys the idea of the presence of a pocket, or depression, such as is visible, for instance, in Fig. 1 of the drawings, numeral 4b. This then is coupled with language from the bottom of page 3 of the specification, that a cap/cover is provided to cover and seal the well in a fluid tight relationship, following deposit of the sample.

Comparing claim 42 to Senior, Senior in contrast has its sample-collecting opening in a narrow end face, and the opening has member 16 filling and protruding out of it, rather than being in the nature of a well with a vacant space in its upper part.

Issue 2 - Claims 43 and 44

The patent of Senior concerns a fundamentally different technology from that forming the basis for the present invention. A declaration of the third joint inventor, Gary Hoffman, under 37 CFR 1.132 was presented with the AMENDMENT of 8/25/00 to explain this different technology referenced in the BACKGROUND of the specification. Only three drops of urine are applied, compared with the massive soaking used in Senior. Claims 43 and 44 were added to present alternative claims specifying the presence of this different technology.

Claim 43 is presented in the format provided in 37 CFR 75(e). The preamble specifies the environment in which the later specified improvement exists. The wording for the preamble incorporates the different technology as compared to Senior, by specifying "a test strip for the immunoassay method called antigen-antibody competitive binding to test a urine sample for drug use" Senior, in contrast, cites pregnancy testing. The preamble also places the well in the broad, lateral face, as described above for claim 42, this in contrast to Senior's placing the sample-receiving orifice in its narrow end face.

Claim 44 brings out the process differences. Urine is dropped into a well and the well then covered, in a drug test. In Senior, the idea is to have a patient urinate onto a protruding bibulous member and then cover the protruding member with a cap.

Issue 3 - Claims 37 to 41

Senior has no disclosure of the interlocking indentions, raised edge and buttons of claims 37 and 38.

Senior does not drop sample (claim 39), more specifically from a pipette (claim 40), into a well/opening containing an empty space, but rather runs a stream of urine against a bibulous member sticking out of, and filling, an opening in the end of its extension 13. Nor does Senior, as in the present claim 39, seal the top of a specially oriented, or located, well/opening of claim 27.

In contrast to the specifications of claim 41, Senior does not place a cartridge/cassette on a photocopier, to photocopy test results showing in a window. Senior mentions a reader/microprocessor, not a photocopier. Details of how Senior's reader/microprocessor works are not disclosed.

The rejection attempts to make up for these lacks by stating that snap fit caps, pipette usage, and photocopying are notoriously well known in the art. Request was made at the top of page 4 of the AMENDMENT filed 8/25/00 that secondary references be cited. MPEP 2144.03. Disconnected items or measures can be known per se and yet patentability may lie in how they are combined, compared to their previous usages. Without citations of previous usage, it is impossible to make this determination.

Rather than cite secondary references, the rejection relies on In re Boesch, 205 USPQ 215. The Boesch decision is inapplicable here. In Boesch, the question was whether it would have been obvious to optimize alloying percentages, knowing that the percentage of particular alloying constituents affected the results. Here, the particular features at issue are not part of a continuum of alloy percentages, within which an optimum is sought; either the features are present, or they are not present. The obviousness of their presence should, instead, be resolved on the basis of the procedure of MPEP Section 2142, according to which three basic criteria must be satisfied, in order to have a valid prima facie obviousness rejection:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Proceeding on this basis, the suggestions in Senior are more: that the cap should not have anything which might make difficult its removal from its first position, for placement into its second position (Senior, col. 3, lines 49-52); that a stream of urine should be applied to member 16 (Senior, col. 4, line 45); and that reader/monitor 41 should be used to record the results (Senior, col. 3, lines 7-41).

Issue 4 - Claims 37-39

Senior has no disclosure of the interlocking indentions, raised edge and buttons of claims 37 and 38. Owens does not have a drawing but mentions a snap fit cap at col. 4, lines 61-63. A rib is mentioned, but not buttons. Ullman provides no structure and only incidentally mentions snap fit at col. 2, line 44.

As pointed out above with respect to Issue 3, Senior discloses a device in which the cap has to be movable, such that snap fits from Owens or Ullman which would make this movement difficult would not have been obvious to one of ordinary skill in the art.

The inclusion of claim 39 in this rejection is not understood, since claim 39 does not mention the snap-together feature.

Conclusion

For the reasons given, the rejections associated with Issues 1 to 4 are not well founded. Reversal of the rejections of all appealed claims 1, 8, 23-34 and 37-44 is in order and is requested.

Respectfully submitted,



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(9) APPENDIX I

A copy of the claims involved in the appeal follows:

1. An assaying device for depositing and analyzing a sample, comprising:

a. a cartridge/cassette means which contains a test strip, a window for viewing test results and a well/opening separate from the window, having a top and serving for deposit of the sample; and

b. a cap/cover means for sealing the top of the sample well/opening in a fluid tight relationship following deposit of the sample.

8. A drug screening device for depositing and analyzing a urine sample, comprising:

a. a cartridge/cassette means which contains a drug test strip, a window for viewing test results and a well/opening separate from the window, having a top and serving for deposit of the urine sample; and

b. a cap/cover means for sealing the top of the sample well/opening in a fluid tight relationship following deposit of the sample.

23. A method of using an assaying device as claimed in claim 1, comprising the steps of: depositing the sample into the well/opening; and attaching the cap/cover means to cover and seal the top of the well/opening in a fluid tight relationship.

24. An assaying device as claimed in claim 1, the well/opening extending from its top into the cartridge/cassette means to surround a space for reception of sample.

25. An assaying device as claimed in claim 24, the space being empty.

26. An assaying device as claimed in claim 25, the cap/cover means when sealing the top of the sample well/opening transforming said space into a chamber for retention of sample.

27. An assaying device as claimed in claim 1, the well/opening being situated on a broad, lateral face of the cartridge/cassette means.

28. An assaying device as claimed in claim 27, the cap/cover means when sealing the top of the sample well/opening passing around the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

29. An assaying device as claimed in claim 28, the cap/cover means when sealing the top of the sample well/opening completely encircling the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

30. An assaying device as claimed in claim 27, the well/opening extending from its top into the cartridge/cassette means to surround a space for reception of sample.

31. An assaying device as claimed in claim 30, the space being empty.

32. An assaying device as claimed in claim 31, the cap/cover means when sealing the top of the sample well/opening transforming said space into a chamber for retention of sample.

33. An assaying device as claimed in claim 32, the cap/cover means when sealing the top of the sample well/opening passing around the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

34. An assaying device as claimed in claim 33, the cap/cover means when sealing the top of the sample well/opening completely encircling the cartridge/cassette means, in order to hold the cap/cover means in a fluid tight relationship against the top of the sample well/opening.

37. An assaying device as claimed in claim 1, the cartridge/cassette means having a raised edge and the cap/cover means having indentations, the raised edge and the indentations, when snapped together, insuring the attachment of the cartridge/cassette means with the cap/cover means.

38. An assaying device as claimed in claim 1, the cartridge/cassette means having an indentation and the cap/cover means having a raised button, the indentation and button, when

snapped together, insuring the attachment of the cartridge/cassette means with the cap/cover means.

39. A method of using an assaying device as claimed in claim 31, comprising the steps of: dropping the sample in the form of urine into the well/opening; and attaching the cap/cover means to cover and seal the top of the well/opening in a fluid tight relationship.

40. A method as claimed in claim 39, wherein the dropping is done from a pipette.

41. A method as claimed in claim 23, further comprising, following the step of attaching, the additional steps of placing the cartridge/cassette on a photocopier and photocopying test results showing in the window.

42. An assaying device for depositing and analyzing a sample, comprising:

I. a cartridge/cassette having a broad, lateral face (1a), a narrow, lateral face (1b), and a narrow end face (1c);

A. the cartridge/cassette containing a test strip, a window in the broad, lateral face for viewing test results and, separate from the window, a well in the broad, lateral face to serve for deposit of the sample; and

II. a cap/cover means for covering and sealing the well in a fluid tight relationship following deposit of the sample.

43. In a device, having:

I. a cartridge/cassette having a broad, lateral face (1a), a narrow, lateral face (1b), and a narrow end face (1c);

A. the cartridge/cassette containing

i. a test strip for the immunoassay method called antigen-antibody competitive binding to test a urine sample for drug use,

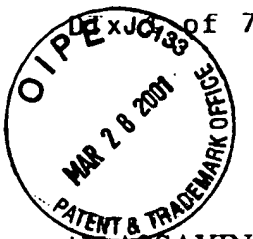
ii. a window in the broad, lateral face for viewing test results and, separate from the window,

iii. a well in the broad, lateral face to serve for deposit of the sample;

the improvement comprising:

II. a cap/cover means for covering and sealing the well in a fluid tight relationship following deposit of the sample.

44. A method of using a device as claimed in claim 43 to test for drug use, comprising the steps of dropping a urine sample into the well and then covering and sealing the well with the cap/cover means in a fluid tight relationship.



APPENDIX II - 08/935,629

Spec as filed
Amended 11/16/98
Amended 7/12/99

AN ASSAYING DEVICE CONSISTING OF THE TEST CARTRIDGE OR CASSETTE WITH A CAP OR COVER WHICH ATTACHES ONTO THE CARTRIDGE OR CASSETTE TO COVER AND SEAL THE WELL OR OPENING INTO WHICH THE SAMPLE HAS BEEN DEPOSITED

5 BACKGROUND

This invention generally relates to assaying devices and in particular the on-site immunoassay technology used to detect the presence of drugs in urine. On-site drug tests generally use an immunoassay method called antigen-antibody competitive binding to screen for the presence of drugs. Among the test kits used for such testing there are tests
10 composed of a housing or container which contains a reagent test strip, an opening in which test results are displayed and a place for deposit of the sample. The sample wicks up into the reagent test strip and the results are displayed. The results are generally available within a few minutes. Often it is desirable to make a photocopy of the results, whether positive or negative, for a permanent record, since test results will change or
15 disappear over time.

Possible problems include spilling of the sample, contamination of the sample, and contact by the test administrator or others with the sample during handling. A method is needed for a cleaner, more sanitary and easier handling of the test housing during and after the test administration, especially since specimens can be infectious. In order to photocopy
20 the results, the test device is placed face down on the copier, so it is desirable to insure that sample will not leak onto the copier. Also a method is needed to insure a second sample from another donor is not inadvertently placed in the same test cartridge/cassette.

SUMMARY OF THE INVENTION

The housing or cartridge/cassette of the present invention will have one or two openings
25 or "windows" in which the test results are displayed and one or two wells or openings in the top of the cartridge/cassette for deposit of the sample. The sample is placed in the

well/opening by use of a pipette. The results will be displayed in the window. The cartridge/cassette and the cap or cover of the present invention will prevent the sample used in the test from spilling out, will prevent contamination of the sample, and will permit cleaner, more sanitary and easier handling of the cartridge/cassette during and after the wicking test process. The cap/cover when placed on the cartridge/cassette will provide a fluid tight relationship. The cartridge/cassette with the cap/cover provide a compact, easy to handle unit. The cap/cover if placed on the cartridge/cassette as soon as the sample begins wicking will prevent inadvertent commingling or intermixing of another sample.

It is the principal object of this invention to provide a convenient, compact, easily managed device for the containment of the sample.

It is also a further objective to provide a means to protect the sample from contamination once placed into the test well/opening.

It is a further objective to provide a means to protect the test administrator from undesirable contact with the sample while handling the test cartridge during the test administration.

It is a further objective to provide a means to protect the test administrator or others from undesirable contact with the sample during subsequent handling of the test cartridge.

It is a further objective of the present invention to provide a means of insuring that while photocopying the test results displayed in the test cartridge/cassette the sample will not leak from the well/opening onto the copier.

It is a further objective of the present invention to provide a means to prevent the test administrator from inadvertently commingling or intermixing a second sample from another donor.

These and other objects of the present invention will become readily apparent upon further review of the following specifications and drawings.

BRIEF DESCRIPTION OF THE DRAWING

In the Drawing:

Figure 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top;

5 Figure 2 is a perspective view of the cartridge/cassette and cap/cover snapped or slipped together as seen from the front;

Figure 3 is a perspective view of the cartridge/cassette with two windows and two sample well/openings and the cap/cover separately as seen from the front or top.

10 Figure 4 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of edges on the cartridge/cassette and indentations on the cap/cover for further securing the cap/cover.

Figure 5 is a side view of the cartridge/cassette and of the cap/cover (shown in cross section) showing the addition of indentations on the cartridge/cassette and raised buttons on the cap/cover for further securing the cap/cover.

15 DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a perspective view of the cartridge/cassette and cap/cover separately as seen from the front or top. The cartridge/cassette 1 contains an opening or window 2 in which the results on the test strip 3 will be displayed. ① The sample will be dropped into the well/opening ② by means of a pipette. ③ The cap/cover 5 has not been placed onto the 20 cartridge/cassette yet.

Fig. 2 is a perspective view showing the cartridge/cassette and cap/cover snapped or slipped together. ④ Fig. 2 is a view as seen from the front or top. The cartridge/cassette 1 with the results window 2 has the cap/cover 5 snapped or slipped into place. The sample well/opening, 4 in the other Figures, is now covered and sealed by the cap/cover 5 in a 25 fluid tight relationship. ⑤

Fig. 3 shows a cartridge/cassette 1 with two results windows 2, two test strips 3, two sample well/openings with a connecting channel 4 and a separate cap/cover 5. This type of cartridge/cassette will accommodate more separate tests and requires a greater quantity of the sample.

5 Fig. 4 shows a side view of the invention with the side of the cap/cover 5 cut away. The cartridge/cassette 1 is designed with a raised edge 6 and the cap/cover (shown in cross section) with indentations 7 which when snapped together will further insure the attachment.

Fig. 5 shows a side view of the invention with the side of the cap/cover 5 cut away. The
 10 cartridge/cassette 1 is designed with an indentation ⁸ and the cap/cover (shown in cross section) with a raised button ⁹ which when snapped together will further insure the attachment. The end of the cartridge/cassette where the well/opening is located has been reduced in thickness with the result that when the cap/cover is attached it will be flush with the edges of the cassette/cover.

15 What is claimed is new and to be protected as set forth in the appended claims. Obviously although the embodiments described herein are the preferred one, modifications can be made to the shape of the cartridge/cassette and the cap/cover, without departing from the spirit and scope of this invention. The cartridge/cassette and the cap/cover may be formed or molded from any suitable material, usually plastic or other similar material, but
 20 the invention should work as well with most drug test materials. The cap is effective if it slips onto the cartridge/cassette snugly enough to insure that it will cover and seal the top of the sample well in a fluid tight relationship and will not detach. Raised buttons or edges can also be incorporated into the design of the cartridge/cassette and cap/cover to further insure that the cap/cover when snapped or slipped into place will not detach from the
 25 cartridge/cassette. The number of windows and urine well/openings shown are currently available, but more will not depart from the spirit and scope of this invention.



ABSTRACT

An assaying device composed of a test cartridge/cassette and cap/cover. When attached, the cap/cover ^{SEALS} the top of a sample well/opening on the cartridge/cassette in a fluid tight manner, to protect ^{TEST} from contact with and contamination of the tested sample (for example, urine
5 for drug testing), provide easier, cleaner handling of the test cartridge/cassette and prevent intermixing of another sample.

(DTx Added Pg. 8)



① Page 3, line 18, between "will be displayed." and "The sample" insert the sentence --As viewed in Fig. 1, cartridge/cassette 1 shows a broad, lateral face 1a, a narrow, lateral face 1b, and a narrow end face 1c.--.

② Page 3, line 19, between "well/opening 4" and "by means" insert --on lateral face 1a--.

③ Page 3, line 19, between "of a pipette." and "The cap/cover" cancel the sentence presented in the AMENDMENT of 11/16/98 and substitute therefor the following revised sentence: --Well/opening 4, which is separate from window 2, has a top in the area of top edge 4a and extends from there into the cartridge/cassette to surround empty space 4b for reception of the sample.--.

④ Page 3, line 22, after "slipped together" and before the first period, insert --following deposit of the sample--.

⑤ Page 3, line 25, after "fluid tight relationship." add --By sealing the top of the sample well/opening, the cap/cover 5 transforms space 4b into a chamber for retention of sample while the sample wicks for the test. As indicated by the cap/cover region 5a showing in Fig. 2, when assembled with the cartridge/cassette, the cap/cover passes around, and, in fact, encircles, the cartridge/cassette, in order to hold the cap/cover in a fluid tight relationship against the top of the sample well/opening.--

APPENDIX III - 08/935,629

*Lawrence filed
Amended 11/16/98*

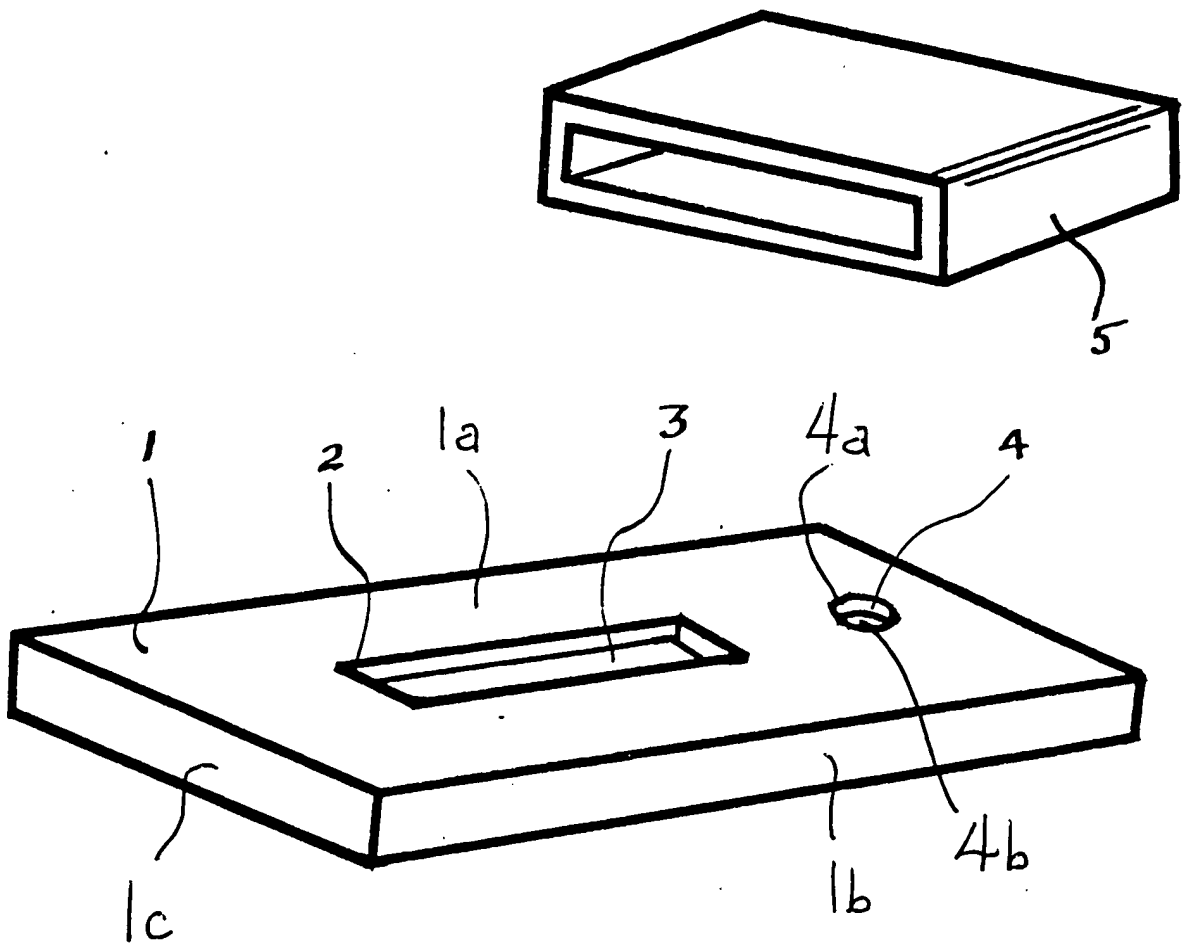


FIG. 1

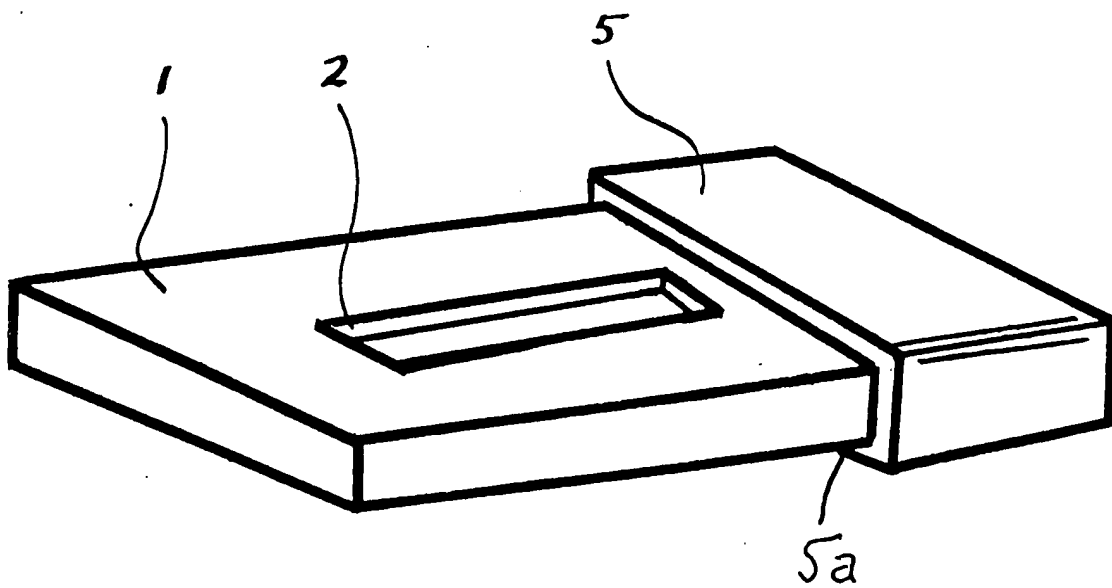


FIG.2

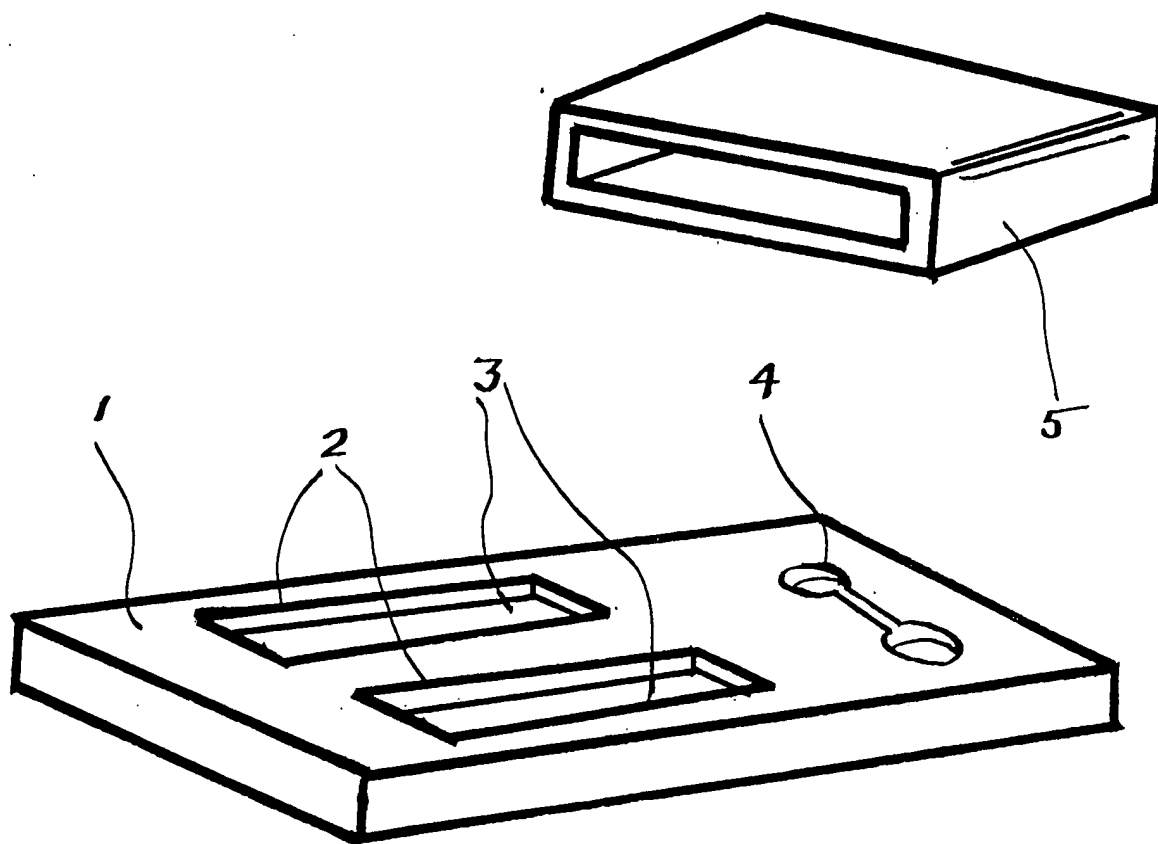


FIG. 3

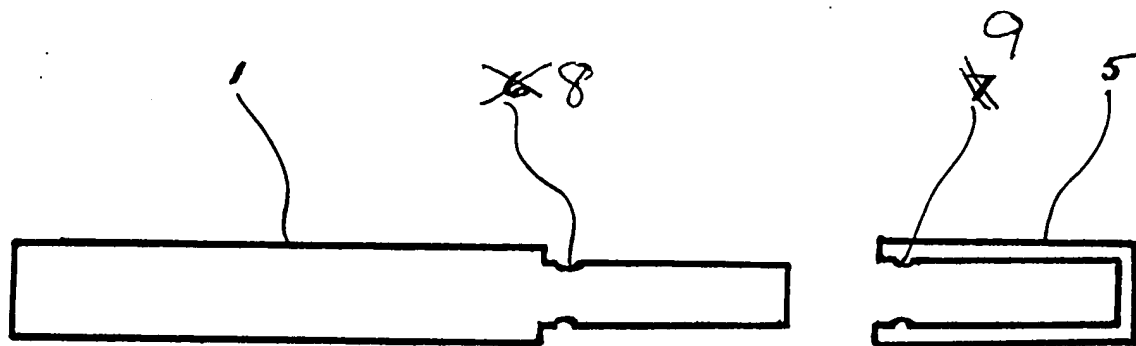
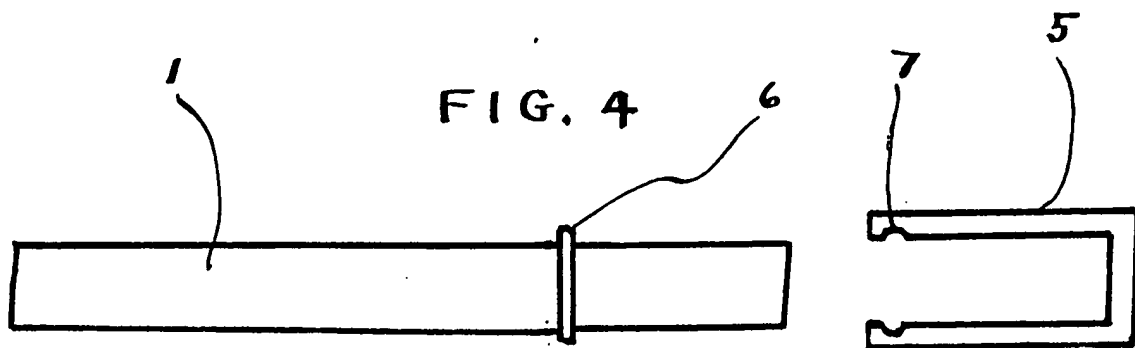


FIG. 5